AMENDED IN ASSEMBLY MAY 11, 2016

AMENDED IN ASSEMBLY APRIL 25, 2016

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL No. 1774

Introduced by Assembly Member Bonilla

February 3, 2016

An act to amend Sections 654.1, 655.5, 1206, 1206.6, 1220, 1244, 1246.5, 1271.1, 1272, 1300, 1301, and 1320 of, to add Section 1272.1 to, to repeal Sections 1241.1, 1265, 1265.1, 1266, 1267, 1268, 1272.4, 1272.6, 1281, 1300.1, 1324, and 1325 of, and to repeal and add Sections 1223, 1227, and 1310 of, the Business and Professions Code, to amend Section 9272 of the Food and Agricultural Code, to amend Sections 1206 and 1600.3 of the Health and Safety Code, and to amend Section 14043.27 of the Welfare and Institutions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1774, as amended, Bonilla. Clinical laboratories: licensure.

Existing federal law, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the federal Centers for Medicare and Medicaid Services to certify and regulate clinical laboratories that perform testing on humans. Complaints against individual laboratories are directed to the state.

Existing law provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health. Under existing law the department inspects clinical laboratories and assesses a fee for licensure of those facilities.

This bill would repeal the laws requiring a clinical laboratory to be licensed by the department, including the licensing fee, and would recast the inspection role of the department to involve inspection and monitoring of specified issues for clinical laboratories that are not accredited by an accrediting organization approved under CLIA, investigation upon complaint, and sanctions, as provided. *The bill would authorize the department, after the balance in the Clinical Laboratory Improvement Fund that is attributable to licensing fees previously assessed on clinical laboratories is less than $1,000,000, to assess a fee, upon inspection, for clinical laboratories that are not accredited by an agency approved under federal law.* The bill would also make conforming changes.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 654.1 of the Business and Professions Code is amended to read:

654.1. (a) A person licensed under Chapter 4 (commencing with Section 1600) of this division or licensed under Chapter 5 (commencing with Section 2000) of this division or licensed under any initiative act referred to in this division relating to osteopaths may not refer patients, clients, or customers to a clinical laboratory in which the licensee has a membership, proprietary interest, or coownership in any form, or has a profit-sharing arrangement, unless the licensee at the time of making the referral discloses in writing the interest to the patient, client, or customer. The written disclosure shall indicate that the patient may choose any clinical laboratory for purposes of having laboratory work or assignment performed.

(b) This does ~~shall~~ not apply to persons who are members of a medical group that contracts to provide medical care to members of a group practice prepayment plan registered under the Knox-Keene Health Care Service Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(c) This does ~~shall~~ not apply to a referral to a clinical laboratory that is owned and operated by a health facility licensed pursuant

to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(d) This section does not prohibit the acceptance of evaluation specimens for proficiency testing or referral of specimens or the assignment from one clinical laboratory to another clinical laboratory, either licensed or exempt under this chapter, providing the report indicates clearly the laboratory performing the test.

(e) "Proprietary interest" does not include ownership of a building where space is leased to a clinical laboratory at the prevailing rate under a straight lease arrangement.

(f) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in a county jail for not more than one year, or by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by a fine not exceeding ten thousand dollars ($10,000), or by both that imprisonment and fine. A second or subsequent conviction shall be punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code.

SEC. 2. Section 655.5 of the Business and Professions Code is amended to read:

655.5. (a) It is unlawful for a person licensed under this division or under an initiative act referred to in this division, or a clinical laboratory, or a health facility when billing for a clinical laboratory of the facility, to charge, bill, or otherwise solicit payment from a patient, client, or customer for a clinical laboratory service not actually rendered by the person or clinical laboratory or under his, ~~her~~ *her,* or its direct supervision unless the patient, client, or customer is apprised at the first time of the charge, billing, or solicitation of the name, address, and charges of the clinical laboratory performing the service. The first written charge, bill, or other solicitation of payment shall separately set forth the name, address, and charges of the clinical laboratory concerned and shall clearly show whether or not the charge is included in the total of the account, bill, or charge. This subdivision is satisfied if the required disclosures are made to the third-party payer of the patient, client, or customer. If the patient is responsible for submitting the bill for the charges to the third-party payer, the bill provided to the patient for that purpose shall include the disclosures required by this section. This subdivision does not apply to a clinical laboratory of a health facility or a health facility when billing for

a clinical laboratory of the facility nor to a person licensed under this division or under any initiative act referred to in this division if the standardized billing form used by the facility or person requires a summary entry for all clinical laboratory charges. For purposes of this subdivision, "health facility" has the same meaning as defined in Section 1250 of the Health and Safety Code.

(b) A clinical laboratory shall provide to each of its referring providers, upon request, a schedule of fees for services provided to patients of the referring provider. The schedule shall be provided within two working days after the clinical laboratory receives the request. For the purposes of this subdivision, a "referring provider" means a provider who has referred a patient to the clinical laboratory in the preceding six-month period. A clinical laboratory that provides a list of laboratory services to a referring provider or to a potential referring provider shall include a schedule of fees for the laboratory services listed.

(c) It is also unlawful for a person licensed under this division or under any initiative act referred to in this division to charge additional charges for a clinical laboratory service that is not actually rendered by the licensee to the patient and itemized in the charge, bill, or other solicitation of payment. This section shall not be construed to prohibit any of the following:

(1) An itemized charge for a service actually rendered to the patient by the licensee.

(2) A summary charge for services actually rendered to a patient by a health facility, as defined in Section 1250 of the Health and Safety Code, or by a person licensed under this division or under any initiative act referred to in this division if the standardized billing form used by the facility or person requires a summary entry for all clinical laboratory charges.

(d) As used in this section, the term "a person licensed under this division" includes a registered laboratory, as defined in Section 1206, all wholly owned subsidiaries of the person, a parent company that wholly owns the person, and any subsidiaries wholly owned by the same parent that wholly owns the person. "Wholly owned" means ownership directly or through one or more subsidiaries. This section shall not apply to billings by a registered laboratory when the registered laboratory bills for services performed by a laboratory owned or operated by the registered laboratory.

(e) This section does not apply to a person or clinical laboratory who or which contracts directly with a health care service plan licensed pursuant to Section 1349 of the Health and Safety Code, if the services are to be provided to members of the plan on a prepaid basis and without additional charge or liability on account thereof.

(f) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in a county jail for not more than one year, or by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by a fine not exceeding ten thousand dollars ($10,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code.

(g) (1) Notwithstanding subdivision (f), a violation of this section by a physician and surgeon for a first offense shall be subject to the exclusive remedy of reprimand by the Medical Board of California if the transaction that is the subject of the violation involves a charge for a clinical laboratory service that is less than the charge would have been if the clinical laboratory providing the service billed a patient, client, or customer directly for the clinical laboratory service, and if that clinical laboratory charge is less than the charge listed in the clinical laboratory's schedule of fees pursuant to subdivision (b).

(2) This subdivision does not permit a physician and surgeon to charge more than he or she was charged for the laboratory service by the clinical laboratory providing the service unless the additional charge is for service actually rendered by the physician and surgeon to the patient.

SEC. 3. Section 1206 of the Business and Professions Code is amended to read:

1206. (a) For the purposes of this chapter the following definitions are applicable:

(1) "Analyte" means the substance or constituent being measured, including, but not limited to, glucose, sodium, or theophylline, or any substance or property whose presence or absence, concentration, activity, intensity, or other characteristics are to be determined.

(2) "Biological specimen" means any material that is derived from the human body.

(3) “Blood electrolyte analysis” means the measurement of electrolytes in a blood specimen by means of ion selective electrodes on instruments specifically designed and manufactured for blood gas and acid-base analysis.

(4) “Blood gas analysis” means a clinical laboratory test or examination that deals with the uptake, transport, and metabolization of oxygen and carbon dioxide in the human body.

(5) “Clinical laboratory test or examination” means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data that may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

(6) “Clinical laboratory science” means any of the sciences or scientific disciplines used to perform a clinical laboratory test or examination.

(7) “Clinical laboratory practice” means the application of clinical laboratory sciences or the use of any means that applies the clinical laboratory sciences within or outside of a licensed or registered clinical laboratory. Clinical laboratory practice includes consultation, advisory, and other activities inherent to the profession.

(8) “Clinical laboratory” means a place used, or an establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. That application may include any means that applies the clinical laboratory sciences.

(9) “Direct and constant supervision” means personal observation and critical evaluation of the activity of unlicensed laboratory personnel by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the unlicensed laboratory personnel are engaged in the duties specified in Section 1269.

(10) “Direct and responsible supervision” means both of the following:

(A) Personal observation and critical evaluation of the activity of a trainee by a physician and surgeon, or by a person licensed under this chapter other than a trainee, during the entire time that the trainee is performing clinical laboratory tests or examinations.

(B) Personal review by the physician and surgeon or the licensed person of all results of clinical laboratory testing or examination performed by the trainee for accuracy, reliability, and validity before the results are reported from the laboratory.

(11) "Licensed laboratory" means a clinical laboratory licensed pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).

(12) "Location" means either a street and city address, or a site or place within a street and city address, where any of the clinical laboratory sciences or scientific disciplines are practiced or applied, or where clinical laboratory tests or examinations are performed.

(13) "Physician office laboratory" means a clinical laboratory that is either: (A) owned and operated by a partnership or professional corporation that performs clinical laboratory tests or examinations only for patients of five or fewer physicians and surgeons or podiatrists who are shareholders, partners, or employees of the partnership or professional corporation that owns and operates the clinical laboratory; or (B) owned and operated by an individual licensed physician and surgeon or a podiatrist, and that performs clinical laboratory tests or examinations only for patients of the physician and surgeon or podiatrist who owns and operates the clinical laboratory.

(14) "Point-of-care laboratory testing device" means a portable laboratory testing instrument to which the following applies:

(A) It is used within the proximity of the patient for whom the test or examination is being conducted.

(B) It is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to paragraph (2) of subdivision (d) of Section 1220.

(C) It meets the following criteria:

(i) Performs clinical laboratory tests or examinations classified as waived or of moderate complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. Sec. 263a).

(ii) Performs clinical laboratory tests or examinations on biological specimens that require no preparation after collection.

(iii) Provides clinical laboratory tests or examination results without calculation or discretionary intervention by the testing personnel.

(iv) Performs clinical laboratory tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning.

(15) "Public health laboratory" means a laboratory that is operated by a city or county in conformity with Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code and the regulations adopted thereunder.

(16) "Registered laboratory" means a clinical laboratory that performs clinical laboratory tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA.

(17) "Specialty" means histocompatibility, microbiology, diagnostic immunology, chemistry, hematology, immunohematology, pathology, genetics, or other specialty specified by regulation adopted by the department.

(18) "Subspecialty" for purposes of microbiology, means bacteriology, mycobacteriology, mycology, parasitology, virology, molecular biology, and serology for diagnosis of infectious diseases, or other subspecialty specified by regulation adopted by the department; for purposes of diagnostic immunology, means syphilis serology, general immunology, or other subspecialty specified by regulation adopted by the department; for purposes of chemistry, means routine chemistry, clinical microscopy, endocrinology, toxicology, or other subspecialty specified by regulation adopted by the department; for purposes of immunohematology, means ABO/Rh Type and Group, antibody detection for transfusion, antibody detection nontransfusion, antibody identification, compatibility, or other subspecialty specified by regulation adopted by the department; for pathology, means tissue pathology, oral pathology, diagnostic cytology, or other subspecialty specified by regulation adopted by the department; for purposes of genetics, means molecular biology related to the diagnosis of human genetic abnormalities,

cytogenetics, or other subspecialty specified by regulation adopted by the department.

(b) This chapter does not restrict, limit, or prevent a person licensed to provide health care services under the laws of this state, including, but not limited to, licensed physicians and surgeons and registered nurses, from practicing the profession or occupation for which he or she is licensed.

(c) This chapter does not authorize a person to perform or order health care services, or utilize the results of the clinical laboratory test or examination, unless the person is otherwise authorized to provide that care or utilize the results. The inclusion of a person in Section 1206.5 for purposes of performing a clinical laboratory test or examination shall not be interpreted to authorize a person, who is not otherwise authorized, to perform venipuncture, arterial puncture, or skin puncture.

SEC. 4. Section 1206.6 of the Business and Professions Code is amended to read:

1206.6. Subdivision (a) of Section 1206.5 does not apply to a pharmacist at a community pharmacy who, upon customer request, performs only blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA and are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, provided that all of the following requirements are satisfied:

(a) The pharmacy obtains a valid CLIA certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations. For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decisionmaking shall be the pharmacist-in-charge, as defined in Section 4036.5.

(b) The pharmacy complies with this chapter.

(c) The tests are performed only by a pharmacist, as defined in Section 4036, in the course of performing routine patient assessment procedures in compliance with Section 4052.4.

SEC. 5. Section 1220 of the Business and Professions Code is amended to read:

1220. (a) (1) Each clinical laboratory shall maintain records, equipment, and facilities that are adequate and appropriate for the services rendered.

(2) (A) Except for tests or examinations classified as waived under CLIA, each clinical laboratory shall enroll, and demonstrate successful participation, as defined under CLIA, for each specialty and subspecialty in which it performs clinical laboratory tests or examinations, in a proficiency testing program approved by the department or by CMS, to the same extent as required by CLIA in Subpart H (commencing with Section 493.801) of Title 42 of the Code of Federal Regulations. This requirement does not prohibit a clinical laboratory from performing clinical laboratory tests or examinations in a specialty or subspecialty for which there is no department or ~~CMS approved~~ *CMS-approved* proficiency testing program.

(B) Each clinical laboratory shall authorize its proficiency test results to be reported to the department in an electronic format that is compatible with the department's proficiency testing data monitoring system and shall authorize the release of proficiency tests results to the public to the same extent required by CLIA.

(b) Each clinical laboratory shall be conducted, maintained, and operated without injury to the public health.

(c) The department shall conduct an investigation of complaints received concerning a clinical laboratory that may include an inspection of the laboratory.

(d) (1) Each clinical laboratory shall perform all clinical laboratory tests or examinations classified as waived under CLIA in conformity with the manufacturer's instructions.

(2) Except for those clinical laboratories performing only tests or examinations classified as waived under CLIA, each clinical laboratory shall establish and maintain all of the following:

(A) A patient test management system that meets the standards of CLIA in Subpart J (commencing with Section 493.1100) of Title 42 of the Code of Federal Regulations.

(B) A quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations as in effect on January 1, 2015, and that may include the clinical laboratory's use of an Individualized Quality Control Plan, as incorporated into Appendix C of the State Operations Manual adopted by the federal Centers for Medicare and Medicaid Services (CMS).

(C) A comprehensive quality assurance program that meets the standards of CLIA in Subpart P (commencing with Section 493.1701) of Title 42 of the Code of Federal Regulations.

SEC. 6. Section 1223 of the Business and Professions Code is repealed.

SEC. 7. Section 1223 is added to the Business and Professions Code, to read:

1223. *(a)* Clinical laboratories shall ~~choose to be overseen~~ *select to be regulated* by the department, pursuant to ~~subdivision (a),~~ *paragraph (1),* or may seek certification of deemed status by an accrediting organization approved under CLIA, pursuant to ~~subdivision (b).~~ *paragraph (2).* The accrediting organization may issue certificates of deemed status and may provide continued oversight to ensure compliance with state law.

~~(a)~~

(1) The department shall monitor, inspect, and investigate all clinical laboratories that are not accredited by an organization approved under CLIA for compliance with state standards that are in excess of federal standards.

~~(b) (1)~~

(2) (A) A clinical laboratory that is accredited by an organization approved under CLIA shall be deemed to meet all state standards and shall not require monitoring, inspection, or investigation pursuant to ~~subdivision (a),~~ *paragraph (1)* but may be subject to investigation by the department under other provisions of law.

~~(2)~~

(B) An accrediting organization shall provide the department with documentation of approval by the federal Centers for Medicare & Medicaid Services as an accrediting body under CLIA, a detailed comparison of the individual accreditation or approval requirements, with the comparable California condition-level requirements, including standards that are in excess of federal law, and a list of all of the clinical laboratories that operate in California, including the CLIA number and the expiration date of their accreditation, as applicable.

~~(c)~~

(b) The department may concentrate its resources on upholding personnel standards.

(c) (1) The department may charge a fee to inspect clinical laboratories that are regulated by the department pursuant to paragraph (1) of subdivision (a). The fee shall be assessed upon inspection and shall be set at the reasonable cost of inspection, but in no case shall the fee exceed one thousand fifty dollars ($1,050).

(2) The department shall not assess a fee pursuant to this subdivision until the balance in the Clinical Laboratory Improvement Fund that is attributable to fees assessed on clinical laboratories under Section 1300, as it existed prior to January 1, 2017, is less than one million dollars ($1,000,000).

SEC. 8. Section 1227 of the Business and Professions Code is repealed.

SEC. 9. Section 1227 is added to the Business and Professions Code, to read:

1227. The department shall post on its Internet Web site a comprehensive list of the differences between state *law* and CLIA.

SEC. 10. Section 1241.1 of the Business and Professions Code is repealed.

SEC. 11. Section 1244 of the Business and Professions Code is amended to read:

1244. *(a)* This chapter does not restrict, limit, or prevent a program of nondiagnostic general health assessment provided that:

(1) The program complies with the requirements of CLIA for waived testing.

(2) The purpose of the program is to screen asymptomatic individuals for chronic health disorders and to refer individuals to licensed sources of care as indicated.

(3) The program does not test for human immunodeficiency virus or any reportable disease or condition identified in Section 120130 of the Health and Safety Code or the regulations adopted under that section.

(4) The program utilizes only those devices that comply with all of the following:

(A) Meet all applicable state and federal performance standards pursuant to Section 111245 of the Health and Safety Code.

(B) Are not adulterated as specified in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(C) Are not misbranded as specified in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(D) Are not new devices unless they meet the requirements of Section 111550 of the Health and Safety Code.

(E) Are approved as waived tests and are used according to the manufacturer's instructions.

(5) Blood collection is performed by skin puncture only.

(6) Testing of a urine specimen is performed by the dipstick method only.

(7) Testing is performed ~~on site~~ *on-site* and reported directly to the person requesting the test.

(8) The program maintains a supervisory committee consisting of, at a minimum, a licensed physician and surgeon and a clinical laboratory scientist licensed pursuant to this code.

(9) The supervisory committee for the program adopts written protocols that shall be followed in the program and that shall contain all of the following:

(A) Provision of written information to individuals to be assessed that shall include, but not be limited to, the following:

(i) The potential risks and benefits of assessment procedures to be performed in the program.

(ii) The limitations, including the nondiagnostic nature, of assessment examinations of biological specimens performed in the program.

(iii) Information regarding the risk factors or markers targeted by the program.

(iv) The need for followup with licensed sources of care for confirmation, diagnosis, and treatment as appropriate.

(B) Proper use of each device utilized in the program including the operation of analyzers, maintenance of equipment and supplies, and performance of quality control procedures including the determination of both accuracy and reproducibility of measurements in accordance with instructions provided by the manufacturer of the assessment device used.

(C) Proper procedures to be employed when collecting blood, if blood specimens are to be obtained.

(D) Proper procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by those biological specimens. These procedures

shall comply with all county and city ordinances for medical waste management and blood-borne pathogen control that apply to the location where the program operates.

(E) Proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.

(F) Documentation that the testing personnel are following the instructions of the instrument's manufacturer, are trained in the performance of the test, and are competent to perform the testing without supervision.

(G) Reporting of assessment results to the individual being assessed.

(H) Referral and followup to licensed sources of care as indicated.

(10) ~~(a)~~ The written protocols adopted by the supervisory committee shall be maintained for at least one year following completion of the assessment program, during which period they shall be subject to review by department personnel and the local health officer or his or her designee, including the public health laboratory director.

(b) If skin puncture to obtain a blood specimen is to be performed in a program of nondiagnostic general health assessment, the individual performing the skin puncture shall be authorized to perform skin puncture under this chapter.

(c) A program of nondiagnostic general health assessment that fails to meet the requirements set forth in subdivisions (a) and (b) shall not operate.

(d) For purposes of this section, "skin puncture" means the collection of a blood specimen by the finger prick method only and does not include venipuncture, arterial puncture, or any other procedure for obtaining a blood specimen.

(e) This chapter does not prohibit a licensed clinical laboratory from operating a program of nondiagnostic general health assessment provided that the clinical laboratory complies with the requirements of this section.

(f) A program for a health fair providing diagnostic or screening tests is not a nondiagnostic general health assessment program if all of the requirements of this chapter are met, and the laboratory performing the testing is licensed by federal law or is operating with a waiver for the applicable procedures. For a test that is not authorized for self-ordering pursuant to Section 1246.5 and that

is not for a nondiagnostic general health assessment pursuant to this section, the clinical laboratory participating in the health fair shall assure that the test is ordered onsite only by a person licensed under this division who is authorized under his or her scope of practice to order the test or by a person authorized by that licensee. The results of a test performed at a health fair shall be provided to the test subject along with an explanation of the results.

SEC. 12. Section 1246.5 of the Business and Professions Code is amended to read:

1246.5. (a) Notwithstanding any other law, a person may request, and a licensed clinical laboratory or public health laboratory may perform, the laboratory tests specified in this section. A registered clinical laboratory may perform the laboratory tests specified in this section if the test is subject to a certificate of waiver under CLIA. A program for nondiagnostic general health assessment that includes a laboratory test specified in this section shall comply with the provisions of Section 1244. The results from any test may be provided directly to the person requesting the test if the test is on or for his or her own body. These test results shall be provided in a manner that presents clear information and that identifies results indicating the need for referral to a physician and surgeon.

(b) The tests that may be conducted pursuant to this section are: pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit. A test approved only as an over-the-counter collection device may not be conducted pursuant to this section.

SEC. 13. Section 1265 of the Business and Professions Code is repealed.

SEC. 14. Section 1265.1 of the Business and Professions Code is repealed.

SEC. 15. Section 1266 of the Business and Professions Code is repealed.

SEC. 16. Section 1267 of the Business and Professions Code is repealed.

SEC. 17. Section 1268 of the Business and Professions Code is repealed.

SEC. 18. Section 1271.1 of the Business and Professions Code is amended to read:

1271.1. (a) A clinical laboratory that provides cytology services shall, if the laboratory ceases operation, preserve records, reports, cytology slides, and cell blocks as prescribed in subdivision (g) of Section 1271 and Section 1274.

(b) A person injured as a result of the laboratory's abandonment of records may bring an action in a court of competent jurisdiction for the amount of damages suffered as a result. If the laboratory was a corporation or partnership that has been dissolved, the person injured may bring an action against that corporation's or partnership's principal officers of record at the time of the dissolution.

(c) For purposes of this section, the following definitions shall apply:

(1) "Abandonment of records" means violating subdivision (a) and thereby leaving patients and physicians and surgeons without access to information to which they are entitled pursuant to this chapter.

(2) "Principal officers" means:

(A) In the case of a partnership other than a limited partnership, any partner.

(B) In the case of a limited partnership, any general partner, as defined in Section 15904.02 of the Corporations Code.

(C) In the case of a corporation, the chairperson of the board, the chief executive officer, and the president of the corporation.

SEC. 19. Section 1272 of the Business and Professions Code is amended to read:

1272. A clinical laboratory shall participate in a CLIA-approved proficiency testing program and demonstrate satisfactory performance in all of the laboratory specialities that include tests performed in the laboratory. Proficiency shall be tested in the following specialties: microbiology, serology, clinical chemistry, hematology, cytology, and immunohematology.

SEC. 20. Section 1272.1 is added to the Business and Professions Code, to read:

1272.1. (a) If a clinical laboratory ceases operations, the laboratory owners, or delegated representatives of the owners, and the laboratory directors shall notify the department of this fact, in writing, within 30 calendar days from the date a clinical laboratory

ceases operation. For purposes of this section, a laboratory ceases operations when it suspends the performance of all clinical laboratory tests or examinations for 30 calendar days at the location for which the clinical laboratory is licensed or registered.

(b) (1) Notwithstanding any other law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required by any other law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.

(2) For purposes of this subdivision, "medical records" means the test requisition or test authorization, or the patient's chart or medical record if used as the test requisition, the final and preliminary test or examination result, and the name of the person contacted if the laboratory test or examination result indicated an imminent life-threatening result or was of panic value.

(3) For purposes of this subdivision, "laboratory records" means records showing compliance with CLIA and this chapter during a laboratory's operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.

(4) Information contained in medical records and laboratory records shall be confidential, and shall be disclosed only to authorized persons in accordance with federal, state, and local laws.

(c) The department or any person injured as a result of a laboratory's abandonment or failure to retain records pursuant to this section may bring an action in a court of proper jurisdiction for any reasonable amount of damages suffered as a result thereof.

SEC. 21. Section 1272.4 of the Business and Professions Code is repealed.

SEC. 22. Section 1272.6 of the Business and Professions Code is repealed.

SEC. 23. Section 1281 of the Business and Professions Code is repealed.

SEC. 24. Section 1300 of the Business and Professions Code is amended to read:

1300. The amount of application and license fees under this chapter shall be as follows:

(a) The application fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical cytogeneticist's, or clinical genetic molecular biologist's license is sixty-three dollars ($63).

(b) The annual renewal fee for a histocompatibility laboratory director's, clinical laboratory bioanalyst's, clinical chemist's, clinical microbiologist's, clinical laboratory toxicologist's, clinical cytogeneticist's, or clinical genetic molecular biologist's license is sixty-three dollars ($63).

(c) The application fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is thirty-eight dollars ($38).

(d) The application and annual renewal fee for a cytotechnologist's license is fifty dollars ($50).

(e) The annual renewal fee for a clinical laboratory scientist's or limited clinical laboratory scientist's license is twenty-five dollars ($25).

(f) The application fee for a trainee's license is thirteen dollars ($13).

(g) The annual renewal fee for a trainee's license is eight dollars ($8).

(h) The application fee for a duplicate license is five dollars ($5).

(i) The personnel licensing delinquency fee is equal to the annual renewal fee.

(j) The director may establish a fee for examinations required under this chapter. The fee shall not exceed the total cost to the department in conducting the examination.

(k) The state, a district, city, county, city and county, or other political subdivision, or a public officer or body shall be subject to the payment of fees established pursuant to this chapter or regulations adopted thereunder.

(*l*) The department shall establish an application fee and a renewal fee for a medical laboratory technician license, the total fees collected not to exceed the costs of the department for the

implementation and operation of the program licensing and regulating medical laboratory technicians pursuant to Section 1260.3.

SEC. 25. Section 1300.1 of the Business and Professions Code is repealed.

SEC. 26. Section 1301 of the Business and Professions Code is amended to read:

1301. (a) The department shall give written notice to all persons licensed pursuant to Section 1260, 1260.1, 1261, 1261.5, 1262, 1264, or 1270 at least 30 days in advance of the regular renewal date that a renewal fee has not been paid. In addition, the department shall give written notice to licensed clinical laboratory bioanalysts or doctoral degree specialists and clinical laboratory scientists or limited clinical laboratory scientists by registered or certified mail 90 days in advance of the expiration of the fifth year that a renewal fee has not been paid and, if not paid before the expiration of the fifth year of delinquency, the licensee may be subject to reexamination.

(b) If the renewal fee is not paid for five or more years, the department may require an examination before reinstating the license, except that an examination shall not be required as a condition for reinstatement if the original license was issued without an examination. An examination shall not be required for reinstatement if the license was forfeited solely by reason of nonpayment of the renewal fee if the nonpayment was for less than five years.

(c) If the license is not renewed within 60 days after its expiration, the licensee, as a condition precedent to renewal, shall pay the delinquency fee identified in subdivision (i) of Section 1300, in addition to the renewal fee in effect on the last preceding regular renewal date. Payment of the delinquency fee is not necessary if, within 60 days of the license expiration date, the licensee files an application for inactive status.

SEC. 27. Section 1310 of the Business and Professions Code is repealed.

SEC. 28. Section 1310 is added to the Business and Professions Code, to read:

1310. (a) If the department determines that a clinical laboratory does not substantially meet the requirements of this chapter or federal law, the department may impose any of the following:

(1) Directed plans of correction, as defined under CLIA.

(2) Civil money penalties in an amount ranging from fifty dollars ($50) to three thousand dollars ($3,000) per day of noncompliance, or per violation, for a condition-level deficiency that does not pose immediate jeopardy, to an amount ranging from three thousand fifty dollars ($3,050) to ten thousand dollars ($10,000) per day of noncompliance, or per violation, for a condition-level deficiency that poses immediate jeopardy, but only after notice and an opportunity to respond in accordance with Section 100171 of the Health and Safety Code, and consideration of facts enumerated in CLIA in Section 493.1834 of Title 42 of the Code of Federal Regulations.

(3) Civil money penalties in an amount ranging from fifty dollars ($50) to three thousand dollars ($3,000) per day of noncompliance, or per violation, for failure to comply with disease reporting requirements, but only after notice and an opportunity to respond in accordance with Section 100171 of the Health and Safety Code.

(4) Onsite monitoring, as defined under CLIA, and payment for the costs of onsite monitoring.

(5) Any combination of the actions described in paragraphs (1) to (4), inclusive.

(b) The department or its agents may enter and inspect a clinical laboratory at any time to enforce state laws and regulations, including, but not limited to, state standards that are more stringent than federal standards.

(c) The costs to the department in conducting a complaint investigation, imposing sanctions, or conducting a hearing under this chapter shall be paid by the clinical laboratory. The fee shall not exceed the fee that the clinical laboratory would pay under CLIA for the same type of activity and shall not be payable if the clinical laboratory would not be required to pay those fees under CLIA.

SEC. 29. Section 1320 of the Business and Professions Code is amended to read:

1320. The department may deny, suspend, or revoke a license issued pursuant to this chapter for any of the following reasons:

(a) Conduct involving moral turpitude or dishonest reporting of tests.

(b) Violation by the applicant or licensee of this chapter or a rule or regulation adopted pursuant thereto.

(c) Aiding, abetting, or permitting the violation of this chapter, the rules or regulations adopted pursuant to this chapter, or the Medical Practice Act (Chapter 5 (commencing with Section 2000) of Division 2).

(d) Permitting a licensed trainee to perform tests or procure specimens unless under direct and responsible supervision.

(e) Violation of any provision of this code governing the practice of medicine and surgery.

(f) Proof that an applicant or licensee has made false statements in any material regard on the application for a license or renewal issued pursuant to this chapter.

(g) Conduct inimical to the public health, morals, welfare, or safety of the people of the State of California in the provision of services for which a license is issued pursuant to this chapter.

(h) Proof that the applicant or licensee has used a degree or certificate as a means of qualifying for licensure that has been purchased or procured by barter or by any unlawful means or obtained from an institution that, at the time the degree, certificate, or title was obtained, was not recognized or accredited by the department of education of the state where the institution is or was located to give training in the field of study in which the degree, certificate, or title is claimed.

(i) Violation of any of the prenatal laws or regulations pertaining thereto in Chapter 2 (commencing with Section 120675) of Part 3 of Division 105 of the Health and Safety Code and Article 1 (commencing with Section 1125) of Group 4 of Subchapter 1 of Chapter 2 of Part 1 of Title 17 of the California Code of Regulations.

(j) Knowingly accepting an assignment for clinical laboratory tests or specimens from, and the rendering of a report thereon to, persons not authorized by law to submit those specimens or assignments.

(k) Rendering a report on clinical laboratory work actually performed in another clinical laboratory without designating clearly the name and address of the laboratory in which the test was performed.

(*l*) Conviction of a felony or misdemeanor involving moral turpitude under the laws of any state or of the United States arising out of or in connection with the practice of clinical laboratory

technology. The record of conviction or a certified copy thereof shall be conclusive evidence of that conviction.

(m) Unprofessional conduct.

(n) The use of drugs or alcoholic beverages to the extent or in a manner as to be dangerous to a person licensed under this chapter, or any other person to the extent that use impairs the ability of the licensee to conduct, with safety to the public, the practice of clinical laboratory technology.

(o) Misrepresentation in obtaining a license.

(p) Performance of a clinical laboratory test or examination or other procedure that is not within the specialties or subspecialties, or category of laboratory procedures authorized by the license.

SEC. 30. Section 1324 of the Business and Professions Code is repealed.

SEC. 31. Section 1325 of the Business and Professions Code is repealed.

SEC. 32. Section 9272 of the Food and Agricultural Code is amended to read:

9272. The provisions of this chapter shall not apply (1) to facilities primarily engaged in the collection, preparation, testing, processing, storage, or distribution of human blood or blood products, provided the facility is licensed pursuant to Chapter 4 (commencing with Section 1600) of Division 2 of the Health and Safety Code and any biologic, as defined in Section 9203, produced by the facility is sold or distributed only to an establishment licensed by this chapter or (2) to clinical laboratories whose only biologics are autogenous bacterins prepared at the request of licensed veterinarians.

SEC. 33. Section 1206 of the Health and Safety Code is amended to read:

1206. This chapter does not apply to the following:

(a) Except with respect to the option provided with regard to surgical clinics in paragraph (1) of subdivision (b) of Section 1204 and, further, with respect to specialty clinics specified in paragraph (2) of subdivision (b) of Section 1204, a place or establishment owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession, within the scope of their license, regardless of the name used publicly to identify the place or establishment.

(b) A clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies, and any primary care clinic specified in subdivision (a) of Section 1204 that is directly conducted, maintained, or operated by this state or by any of its political subdivisions or districts, or by any city. Nothing in this subdivision precludes the department from adopting regulations that utilize clinic licensing standards as eligibility criteria for participation in programs funded wholly or partially under Title XVIII or XIX of the federal Social Security Act.

(c) (1) A clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1603 of Title 25 of the United States Code, that is located on land recognized as tribal land by the federal government.

(2) A clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1603 of Title 25 of the United States Code, under a contract with the United States pursuant to the Indian Self-Determination and Education Assistance Act (Public Law 93-638), regardless of the location of the clinic, except that if the clinic chooses to apply to the State Department of Public Health for a state facility license, then the State Department of Public Health will retain authority to regulate that clinic as a primary care clinic as defined by subdivision (a) of Section 1204.

(d) Clinics conducted, operated, or maintained as outpatient departments of hospitals.

(e) A facility licensed as a health facility under Chapter 2 (commencing with Section 1250).

(f) A freestanding clinical or pathological laboratory.

(g) A clinic operated by, or affiliated with, an institution of learning that teaches a recognized healing art and is approved by the state board or commission vested with responsibility for regulation of the practice of that healing art.

(h) A clinic that is operated by a primary care community or free clinic and that is operated on separate premises from the licensed clinic and is only open for limited services of no more than 30 hours a week. An intermittent clinic, as described in this subdivision, shall meet all other requirements of law, including

administrative regulations and requirements, pertaining to fire and life safety.

(i) The offices of physicians in group practice who provide a preponderance of their services to members of a comprehensive group practice prepayment health care service plan subject to Chapter 2.2 (commencing with Section 1340).

(j) Student health centers operated by public institutions of higher education.

(k) Nonprofit speech and hearing centers, as defined in Section 1201.5. A nonprofit speech and hearing clinic desiring an exemption under this subdivision shall apply to the director, who shall grant the exemption to any facility meeting the criteria of Section 1201.5. Notwithstanding the licensure exemption contained in this subdivision, a nonprofit speech and hearing center shall be deemed to be an organized outpatient clinic for purposes of qualifying for reimbursement as a rehabilitation center under the Medi-Cal Act (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

(*l*) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, that conducts medical research and health education and provides health care to its patients through a group of 40 or more physicians and surgeons, who are independent contractors representing not less than 10 board-certified specialties, and not less than two-thirds of whom practice on a full-time basis at the clinic.

(m) A clinic, limited to in vivo diagnostic services by magnetic resonance imaging functions or radiological services under the direct and immediate supervision of a physician and surgeon who is licensed to practice in California. This shall not be construed to permit cardiac catheterization or any treatment modality in these clinics.

(n) A clinic operated by an employer or jointly by two or more employers for their employees only, or by a group of employees, or jointly by employees and employers, without profit to the operators thereof or to any other person, for the prevention and treatment of accidental injuries to, and the care of the health of, the employees comprising the group.

(o) A community mental health center, as defined in Section 5667 of the Welfare and Institutions Code.

(p) (1) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, as an entity organized and operated exclusively for scientific and charitable purposes and that satisfied all of the following requirements on or before January 1, 2005:

(A) Commenced conducting medical research on or before January 1, 1982, and continues to conduct medical research.

(B) Conducted research in, among other areas, prostatic cancer, cardiovascular disease, electronic neural prosthetic devices, biological effects and medical uses of lasers, and human magnetic resonance imaging and spectroscopy.

(C) Sponsored publication of at least 200 medical research articles in peer-reviewed publications.

(D) Received grants and contracts from the National Institutes of Health.

(E) Held and licensed patents on medical technology.

(F) Received charitable contributions and bequests totaling at least five million dollars ($5,000,000).

(G) Provides health care services to patients only:

(i) In conjunction with research being conducted on procedures or applications not approved or only partially approved for payment (I) under the Medicare program pursuant to Section 1359y(a)(1)(A) of Title 42 of the United States Code, or (II) by a health care service plan registered under Chapter 2.2 (commencing with Section 1340), or a disability insurer regulated under Chapter 1 (commencing with Section 10110) of Part 2 of Division 2 of the Insurance Code; provided that services may be provided by the clinic for an additional period of up to three years following the approvals, but only to the extent necessary to maintain clinical expertise in the procedure or application for purposes of actively providing training in the procedure or application for physicians and surgeons unrelated to the clinic.

(ii) Through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time for the entity operating the clinic, on an annual basis, to direct patient care activities for which charges for professional services are paid.

(H) Makes available to the public the general results of its research activities on at least an annual basis, subject to good faith protection of proprietary rights in its intellectual property.

(I) Is a freestanding clinic, whose operations under this subdivision are not conducted in conjunction with any affiliated or associated health clinic or facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "affiliated" only if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "associated" only if more than 20 percent of the directors or trustees of the clinic are also the directors or trustees of any individual clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). Any activity by a clinic under this subdivision in connection with an affiliated or associated entity shall fully comply with the requirements of this subdivision. This subparagraph shall not apply to agreements between a clinic and any entity for purposes of coordinating medical research.

(2) By January 1, 2007, and every five years thereafter, the Legislature shall receive a report from each clinic meeting the criteria of this subdivision and any other interested party concerning the operation of the clinic's activities. The report shall include, but not be limited to, an evaluation of how the clinic impacted competition in the relevant health care market, and a detailed description of the clinic's research results and the level of acceptance by the payer community of the procedures performed at the clinic. The report shall also include a description of procedures performed both in clinics governed by this subdivision and those performed in other settings. The cost of preparing the reports shall be borne by the clinics that are required to submit them to the Legislature pursuant to this paragraph.

SEC. 34. Section 1600.3 of the Health and Safety Code is amended to read:

1600.3. "Blood bank depository" means a place other than a blood bank where human whole blood and human whole blood derivatives specified by regulation are stored and held for

transfusion. Blood bank depositories shall be clinical laboratories, licensed in accordance with the provisions of federal law, or other places where services essentially equivalent are maintained, as determined by the department.

SEC. 35. Section 14043.27 of the Welfare and Institutions Code is amended to read:

14043.27. (a) If an applicant or provider is granted provisional provider status or preferred provisional provider status pursuant to Section 14043.26 and, if at any time during the provisional provider status period or preferred provisional provider status period, the department conducts any announced or unannounced visits or any additional inspections or reviews pursuant to this chapter or Chapter 8 (commencing with Section 14200), or the regulations adopted thereunder, or pursuant to Section 100185.5 of the Health and Safety Code, and discovers or otherwise determines the existence of any ground to deactivate the provider's number and business addresses or suspend the provider from the Medi-Cal program pursuant to this chapter or Chapter 8 (commencing with Section 14200), or the regulations adopted thereunder, or pursuant to Section 100185.5 of the Health and Safety Code, or if any of the circumstances listed in subdivision (c) occur, the department shall terminate the provisional provider status or preferred provisional provider status of the provider, regardless of whether the period of time for which the provisional provider status or preferred provisional provider status was granted under Section 14043.26 has elapsed.

(b) Termination of provisional provider status or preferred provisional provider status shall include deactivation of the provider's number, including all business addresses used by the provider to obtain reimbursement from the Medi-Cal program and removal of the provider from enrollment in the Medi-Cal program, except where the termination is based upon a ground related solely to a specific location for which provisional provider status was granted. Termination of provisional provider status based upon grounds related solely to a specific location may include failure to have an established place of business, failure to possess the business or zoning permits or other approvals necessary to operate a business, or failure to possess the appropriate licenses, permits, or certificates necessary for the provider of service category or subcategory identified by the provider in its application package.

Where the grounds relate solely to a specific location, the termination of provisional provider status shall include only deactivation of the specific locations that the grounds apply to and shall include removal of the provider from enrollment in the Medi-Cal program only if, after deactivation of the specific locations, the provider does not have any business address that is not deactivated.

(c) The following circumstances are grounds for termination of provisional provider status or preferred provisional provider status:

(1) The provider, persons with an ownership or control interest in the provider, or persons who are directors, officers, or managing employees of the provider have been convicted of any felony, or convicted of any misdemeanor involving fraud or abuse in any government program, related to neglect or abuse of a patient in connection with the delivery of a health care item or service, or in connection with the interference with, or obstruction of, any investigation into health care related fraud or abuse, or have been found liable for fraud or abuse in any civil proceeding, or have entered into a settlement in lieu of conviction for fraud or abuse in any government program within 10 years of the date of the application package.

(2) There is a material discrepancy in the information provided to the department, or with the requirements to be enrolled, that is discovered after provisional provider status or preferred provisional provider status has been granted and that cannot be corrected because the discrepancy occurred in the past.

(3) The provider has provided material information that was false or misleading at the time it was provided.

(4) The provider failed to have an established place of business at the business address for which the application package was submitted at the time of any onsite inspection, announced or unannounced visit, or any additional inspection or review conducted pursuant to this article or a statute or regulation governing the Medi-Cal program, unless the practice of the provider's profession or delivery of services, goods, supplies, or merchandise is such that services, goods, supplies, or merchandise are rendered or delivered at locations other than the business address and this practice or delivery of services, goods, supplies, or merchandise has been disclosed in the application package

approved by the department when the provisional provider status or preferred provisional provider status was granted.

(5) The provider meets the definition of a clinic under Section 1200 of the Health and Safety Code, but is not licensed as a clinic pursuant to Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code and fails to meet the requirements to qualify for at least one exemption pursuant to Section 1206 or 1206.1 of the Health and Safety Code.

(6) The provider performs clinical laboratory tests or examinations, but it or its personnel do not meet CLIA, and the regulations adopted thereunder, do not possess valid CLIA certificates, or are not exempt pursuant to Section 1241 of the Business and Professions Code.

(7) The provider fails to possess either of the following:

(A) The appropriate licenses, permits, certificates, or other approvals needed to practice the profession or occupation, or provide the services, goods, supplies, or merchandise the provider identified in the application package approved by the department when the provisional provider status or preferred provisional provider status was granted and for the location for which the application was submitted.

(B) The business or zoning permits or other approvals necessary to operate a business at the location identified in its application package approved by the department when the provisional provider status or preferred provisional provider status was granted.

(8) The provider, or if the provider is a clinic, group, partnership, corporation, or other association, any officer, director, or shareholder with a 10 percent or greater interest in that organization, commits two or more violations of the federal or state statutes or regulations governing the Medi-Cal program, and the violations demonstrate a pattern or practice of fraud, abuse, or provision of unnecessary or substandard medical services.

(9) The provider commits any violation of a federal or state statute or regulation governing the Medi-Cal program or of a statute or regulation governing the provider's profession or occupation and the violation represents a threat of immediate jeopardy or significant harm to any Medi-Cal beneficiary or to the public welfare.

(10) The provider submits claims for payment that subject a provider to suspension under Section 14043.61.

(11) The provider submits claims for payment for services, goods, supplies, or merchandise rendered at a location other than the business address or addresses listed on the application for enrollment, unless the practice of the provider's profession or delivery of services, goods, supplies, or merchandise is such that services, goods, supplies, or merchandise are rendered or delivered at locations other than the business address and this practice or delivery of services, goods, supplies, or merchandise has been disclosed in the application package approved by the department when the provisional provider status was granted.

(12) The provider has not paid its fine, or has a debt due and owing, including overpayments and penalty assessments, to any federal, state, or local government entity that relates to Medicare, ~~medicaid,~~ *Medicaid*, Medi-Cal, or any other federal or state health care program, and has not made satisfactory arrangements to fulfill the obligation or otherwise been excused by legal process from fulfilling the obligation.

(d) If, during a provisional provider status period or a preferred provisional provider status period, the department conducts any announced or unannounced visits or any additional inspections or reviews pursuant to this chapter or Chapter 8 (commencing with Section 14200), or the regulations adopted thereunder, and commences an investigation for fraud or abuse, or discovers or otherwise determines that the provider is under investigation for fraud or abuse by any other state, local, or federal government law enforcement agency, the provider shall be subject to termination of provisional provider status or preferred provisional provider status, regardless of whether the period of time for which the provisional provider status or preferred provisional provider status was granted under Section 14043.26 has elapsed.

(e) A provider whose provisional provider status or preferred provisional provider status has been terminated pursuant to this section may appeal the termination in accordance with Section 14043.65.

(f) Any department-recovered fine or debt due and owing, including overpayments, that are subsequently determined to have been erroneously collected shall be promptly refunded to the

provider, together with interest paid in accordance with subdivision (e) of Section 14171 and Section 14172.5.

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